510(k) Summary

JAN 3 1 2014

Contact: Justin Eggleton
Musculoskeletal Clinical & Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
202.552.5800

Date Prepared: January 17, 2014

Device Trade Name: Aurora Spine Interbody Fusion System

Sponsor: Aurora Spine, Inc.
1920 Palomar Point Way
Carlsbad, CA 92008

Common Name: Lumbar and Cervical Interbody Cage

Classification: 21 CFR §888.3080; Intervertebral body fusion device

Class: II

Product Code: MAX, ODP

Indications For Use:

Lumbar System Indications
The Aurora Spine Interbody Fusion System devices are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Patients should have six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and are placed via either a posterior, transforaminal, lateral or anterior approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with supplemental fixation systems cleared for use in the thoracolumbar spine.

Cervical System Indications
The Aurora Spine Interbody Fusion System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one level of the cervical spine with accompanying radicular symptoms. Patients should have six weeks of non-operative treatment prior to surgery. Cervical implants are used to facilitate fusion in the cervical spine (C2-T1) and are placed

via an anterior approach using autogenous bone. When used as an interbody fusion device, supplemental fixation must be used.

Device Description:
The Aurora Spine Interbody Fusion System, manufactured from PEEK-Optima®, consist of implants available in various foot prints, heights and lordotic configurations with an open architecture to accept packing of autograft materials. The exterior of the device has "teeth" or other generally sharp engagement members on the superior and inferior surfaces to help prevent the device from migrating once it is surgically positioned. The device comes in a PEEK or PEEK with a plasma-sprayed commercially pure titanium coating on the superior and inferior surfaces.

Predicate Device(s):
The Aurora Spine Interbody Fusion System was shown to be substantially equivalent to previously cleared device and has the same indications for use, design, function, and materials used. This device is the Tyber Medical Interbody System (K130573).

Performance Standards:
Non-clinical mechanical testing was performed consisting of Static and Dynamic Compression, Torsion, Compression-Shear per ASTM F2077. Additionally, Subsidence Testing per ASTM F2267 and Expulsion testing was performed. The coating characterization tests include Static Shear per ASTM F1044, Static Tension per ASTM F1147, and Abrasion per ASTM F1978. All data indicates the device is substantial equivalence to the predicate systems

Clinical data and conclusions were not needed for this device.

Conclusion:
The Aurora Spine Interbody Fusion System is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 31, 2014

Aurora Spine
% Mr. Justin Eggleton
Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street Northwest, 12th Floor
Washington, District of Columbia 20005

Re: K133967
Trade/Device Name: Aurora Spine Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: December 18, 2013
Received: December 24, 2013

Dear Mr. Eggleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indications for Use

510(k) Number (if known): K133967

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Prescription Use ___V___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices